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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,743	08/19/2003	Real Lemieux	701826-054340	4127

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
06/13/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/643,743	LEMIEUX ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-8,11,12 and 14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10,13,19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/13/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/08 has been entered.

2. Claims 9,10,13,19-21 are under consideration.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9,10,13,19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a)There is no support in the specification as originally filed for the recitation of "wherein said autoantibodies are highly enriched in ferritin-binding antibodies" in claim 9. Regarding applicants comments about the cited passages of the specification, said passages refer to a particular experiment that uses particular techniques to achieve a particular experimental result. The claims encompass a composition "highly enriched in ferritin-binding antibodies" wherein the antibodies are enriched by techniques other than that disclosed in the specific example wherein the degree of purity could be greater or lesser than that disclosed in the specific example disclosed in the specification. The claims would also encompass use of experimental protocols other than specifically disclosed in the example that resulted in greater or lesser purity than the specific example disclosed in the specification.

b) There is no support in the specification as originally filed for the recitation of "inhibiting" in claim 10. Regarding applicants comments, the original claim 10 recites

that the autoimmune complexes are capable of activating complement in human serum. None of the cited passages disclose that the autoantibodies are capable of inhibiting complement in human serum.

c) There is no support in the specification as originally filed for claim 19. Regarding applicants comments, Table 2 describes a single experiment that achieves a single specific degree of purity. The experiment does not disclose antibodies that are encompassed by the degree of purity recited in the claim (10000 fold or 21 fold or 26 fold or 37 fold, etc).

d) There is no support in the specification as originally filed for claims 20 and 21. Regarding the cited passages of the specification, said examples disclose specific experimental parameters that are not recited in the claims. The limitation under consideration encompasses use of any affinity chromatography procedure wherein the specification is limited to a disclosure of a specific experimental system using specifically defined parameters.

There is no written description of the scope of the claimed inventions in the specification as filed (aka the claimed inventions constitute new matter).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9,10,13,19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation of “ferritin binding antibodies” because it is unclear as what said term means or encompasses. Conventional antibodies bind a single antigen and generally do not react with unrelated antigens. However, according to the specification, the “ferritin binding antibodies” of the instant invention also bind other autoantigens and tested antigens (see [0047]). However, based on said disclosure it is unclear as to whether said antibodies bind all autoantigens and antigens or whether they have some specificity for a subsets of autoantigens. According to the Lemieux declaration, there is some

difference between the claimed antibodies and antiDNP antibodies which also bind autoantigens (as per Bourel et al). However, there is no disclosure in the specification as what this difference in specificity is. Thus, it is unclear as to what the specificity of the claimed antibodies encompasses. It is unclear whether the claimed antibodies bind all autoantigens or a subset of autoantigens and what other antigens other than autoantigens are bound by said antibodies. If the claimed antibodies bind all autoantigens then it is unclear to how they would differ from antiDNP antibodies which also bind autoantigens. For the purposes of prior art the claimed antibodies will be interpreted as binding all autoantigens.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 9,10,13,19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourel et al. (EP 1059088 A1).

Bourel et al. disclose purified autoantibodies isolated from IVIg, wherein said autoantibodies bind DNP-Lysine (aka DNP-haptene) or IgM or IgG (see abstract, claims 1-3,9 [0010], [0001], [0014]) and also bind autoantigens (see Tables). Bourel et al. disclose a composition of said antibodies and a pharmaceutically acceptable carrier (see [0070]). It is an inherent property of said antibodies that said antibodies have the properties recited in the claims because they are enriched for the same autoantibodies. The preparation is inherently enriched for ferritin binding autoantibodies because the three preparations are highly enriched for autoantibodies which bind self antigens (see Tables 3 and 4) wherein the preparations are greater than 20 fold enriched for autoantibodies against human antigens. Furthermore, as per the specification, section [00047], the anti ferritin antibodies recited in the claims are not conventional monoreactive antibodies, but are polyreactive antibodies which bind appear to bind

autoantigens per se. The functional properties of said antibodies recited in the claims are an inherent property of autoantibodies which bind soluble human serum proteins. Said antibodies are capable of forming autoimmune complexes because they are antibodies which bind soluble proteins present in human serum. Said autoantibodies have the property of claim 10 because they are the same type of autoantibodies as disclosed in the specification (polyclonal antibodies which bind soluble human serum proteins). The recitation of a process wherein the antibodies are made in the instant claims carries no patentable weight because the claimed product and that of the prior art are the same.

Regarding applicants comments, the Lemieux et al. declaration does not address the purified polyreactive antiautoantigen antiIgM autoantibodies taught by Bourel et al. as per above. Regarding the Lemieux et al. declaration, the coupling method appears to use different reagents from that disclosed by Bourel et al. (page 14) and there is no disclosure as to the amount of DNP-Lysine that was actually coupled to the column. Thus, it is unclear as to whether said data is relevant to the disclosure of Bourel et al. and the disclosed antiDNP autoreactive antibodies. Furthermore, regarding Table 1 in the Lemieux et al. declaration, the results in Table 3 of Bourel et al. indicate that the antiDNP preparation is highly enriched for autoantibodies against several autoantigens including actin wherein the degree of enrichment was similar to that disclosed in Table 2 of the specification. Thus, there is a clear contradiction between the Lemieux declaration and the results disclosed in the specification and the disclosure of Bourel et al. It is therefore also unclear as to the relevance of the data disclosed in Table 1 of Lemieux et al. and the presence of antiferritin antiautoantibodies in the preparation taught by Bourel et al. Furthermore, as per the specification, section [00048], the polyreactive antiferritin antibodies bind all tested autoantigens. Therefore, the presence of autoantibodies in the preparation of Table 3 of Bourel et al. should indicate the presence of polyreactive “anti ferritin antibodies”. Therefore the prior art anticipates the claimed inventions as per above. The Lemieux declaration also does not address the anti IgG autoantibodies that are taught in the prior art and no longer excluded from the claimed invention as per the amended claim 9. Furthermore, according to Bruley-Rosset

et al., anti-DNP autoantibodies isolated from IVIG actually have a higher degree of anticytokine reactivity than IVIG (see page 1017, second column, last paragraph). In addition, regarding Figure 1 in the Lemieux declaration, Bruley-Rosset et al. actually disclose strong binding of anti-DNP autoantibodies isolated from IVIG to actin (see Table 1).

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron, Ph.D./
Primary Examiner, Art Unit 1644